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(54) Suture passer

Instrument zum Durchführen eines Nähfadens

Passe-fil pour suture

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Description

[0001] The present invention relates to the treatment of stress urinary incontinence "SUI" and, in particular, to a suture passer for the surgical treatment of SUI in females.

[0002] Genuine stress incontinence is the involuntary loss of urine due to a sudden rise in intra-abdominal pressure. It has been estimated that between 40% and 50% of young, healthy nulliparous women admit to occasional mild stress incontinence; however, at least 80% of stress incontinence patients are in the perimenopausal age group and are multiparous. Raz[3] has suggested that the female urethral continence mechanism is dependent on the interaction of four urethral factors: urethral closing pressure, urethral length, urethrotrigonal anatomy, and urethral reception of intraabdominal pressure.

[0003] The urethral closing pressure is predominantly a result of the interaction of smooth and striated muscle sphincter activity, but there is also some contribution by nonmuscular urethral factors such as the submucosal vascular plexus, the elastin and collagen content of the urethral tissues, and a sphincter like effect of the mucosa. There has been considerable diversity of opinion regarding the anatomic structure and the innervation of the urethral sphincters, and a variety of views have been expressed in the literature.

[0004] Lapides and associates have stressed the importance of urethral length in the maintenance of continence in the female. However, although it certainly interacts with other factors to contribute to continence, a short urethra alone will not produce incontinence. Urethral length varies considerably in normal women, and women with proven genuine stress urinary incontinence do not invariably have urethral shortening.

[0005] Urethrotrigonal anatomy, which can be demonstrated by lateral cystourethrography, should fulfill certain criteria. The bladder base should lie above the level of the inferior ramus of the symphysis, and with straining should not descend more than 1.5 cm. There should be a normal urethrotrigonal alignment with an angle normally less than 100 degrees, and the urethral axis should be approximately 35 degrees from the vertical. In the hypermobile situation loss of all of the normal anatomic features may occur, a radiologic finding that correlates with the clinical finding of cystourethrocele. However, clinical experience has shown that the coexistence of cystourethrocele and incontinence does not predict that the incontinence is of a genuine stress variety.

[0006] The transmission of intra-abdominal pressure to the intra-abdominal portion of the proximal urethra is also reported to be important in the maintenance of continence. This is a passive phenomenon, and is the result of the normal anatomic configuration just described. Whenever there is a rise in intra-abdominal pressure during such stresses as coughing or straining, the pressure is transmitted not only to the bladder but also to the proximal urethra, with resultant increase in the closing pressure, and prevention of leakage. If the urethral axis is altered, rotational descent will drop the proximal urethra and bladder base from its intra-abdominal location, and will obviously impair such pressure transmission.

[0007] A wide variety of operations have been used to correct this condition, generally involving the principles of elevating the bladder neck anteriorly and/or elongating and narrowing the proximal urethra. Two of the most popular operations today for female stress incontinence are the Marshall-Marchetti-Krantz and Birch vesicourethropexies. The Marshall-Marchetti-Krantz technique has at least an eighty five percent success rate, against which other operative success rates must be measured. Recently, the Pereyra operation and its modifications have enjoyed some popularity, but less than basic techniques.

[0008] Notwithstanding the foregoing, however, there remains a need for an improved treatment for SUI. Preferably, the treatment is as noninvasive as possible under the circumstances, and will eliminate or minimize hospitalization and the use of general anaesthetics. In addition, there remains a need for improved medical instrumentation such as suture passers for use in connection with SUI treatment and other medical procedures.

[0009] The United States Patent U.S. 2,738,790 discloses a stitching instrument for stitching the mitral valve of the heart comprising a body portion to which a flattened tube is secured. The flattened tube terminates before a slot formed in the forward end of the body portion. A needle having a hook portion for grasping a suture is movably disposed in the flattened tube. The known stitching instrument is not suitable for use in the bladder neck suspension procedures here in which a suture is captured inside the body.

[0010] In accordance with the present invention, a suture passer is provided as defined in Claim 1. Embodiments of the suture passer are defined in the dependent claims. The suture passer comprises a handle and an elongate tubular probe guide extending in a distal direction, preferably straight or curved, from the handle. An elongate pointed probe having a recess is axially movable within the tubular probe guide to facilitate penetration of tissue. The tubular probe guide has an opening for receiving a suture, the opening extending radially inwardly into said probe guide and then generally axially along said probe guide towards the distal end thereof.

[0011] The probe is axially movable with respect to the probe guide between a first position in which the recess is aligned with the opening for receiving a suture therein and a second position wherein the recess is out of alignment with the opening to trap or retain a suture within the recess.

[0012] The suture passer of the present invention may be used in a surgical bladder neck suspension proce-

dure, for the treatment of stress urinary incontinence. A technique of creating a suspension web comprising a plurality of lengths of suture is constructed extending between the pubocervical fascia and the pubic bone, on each of the right and left sides of the midline. Sutures are carried through tissue utilizing the suture passer disclosed herein, and sutures are tied down to the pubic bone utilizing a bone anchor positioned on each of the right and left sides of the midline by a drill guide as disclosed herein. Prior to tying, sutures are appropriately tensioned by advancing the suture around the suture tensioner disclosed herein and tying in a conventional manner. Thereafter, the suture tensioner is removed and the surgical site prepared and closed in a conventional manner.

[0013] Additional objects and advantages of the present invention will become apparent from the detailed description of preferred embodiments which follows, when taken together with the attached drawings and claims.

Figure 1 is a cross sectional view of a suture passer in accordance one embodiment of with the present invention.

Figure 2 is an enlargement of the distal tip of the suture passer illustrated in Figure 1.

Figure 3 illustrates the location of incision sites for the method.

Figure 4a represents the positioning of the vertical passage of a Stamey needle or suture passer to just below the rectus fascia.

Figure 4b illustrates the placement of a needle point or suture passer on the underside of the pubic bone.

Figure 4c represents the distal passage of the needle or suture passer to the level of the introitus.

Figure 4d represents the withdrawal of the needle or suture passer from the pubourethral ligament and the path of the sweep back along the pubocervical fascia to the area of the bladder neck and first entry site.

Figure 5a illustrates the initial passage of the needle or suture passer through the pubocervical fascia at point 1 (proximal and medial).

Figure 5b represents the withdrawal of the suture through the pubic wound.

Figure 5c illustrates the passage of the needle or suture passer through the lateral aspect of the pubic wound and through the pubocervical fascia at point 2 (proximal and lateral).

Figure 5d illustrates the withdrawal of the suture into the retropubic space.

Figure 5e illustrates the passage of the needle or suture passer and suture through point 3 (distal and medial).

Figure 5f illustrates withdrawal of the needle or suture passer into the retropubic space.

Figure 5g illustrates the passage of the needle or suture passer through point 4 (distal and lateral).

Figure 5h illustrates the withdrawal of the suture through the pubic wound.

Figure 6 is a cross-sectional view of an alternate embodiment suture passer of the present invention.

Figure 6a is an enlarged view of the distal tip of the suture passer illustrated in Figure 6.

[0014] SUI is generally curable with any of a variety of surgical procedures that properly suspends the bladder neck. However, limitations of known procedures include 1) the extent of surgical morbidity 2) the ever present threat of long tern failures and 3) the reproducibility between different surgeons.

[0015] Pereyra[1] introduced the transvaginal bladder neck suspension as a less invasive alternative to open retropubic procedures. Stamey[2] limited morbidity and improved the reproducibility of the transvaginal bladder neck suspension by introducing endoscopic control and confirmation of suture placement. Raz[3] has improved reproducibility by introducing full palpatory control of needle passage through the retropubic space, thereby limiting disability through injury to the bladder or other retropubic structures.

[0016] The distal passage of the suture passer disclosed herein or other needle followed by a sweep back to the bladder neck area described herein accomplishes a similar goal but without the necessity of entering the retropubic space. Passage of the needle point to the level of the introitus along the underside of the pubic bone obviates the need to turn the needle down toward a bladder neck that has been digitally elevated, thereby reducing the risk of bladder injury. Extraction of the needle from the pubourethral ligament is necessary to allow a "capture" of the more pliable pubocervical fascia alongside the urethra. The subsequent, gentle sweep back of the needle along the surface of the pubocervical fascia provides an easy and safe means of introducing the needle to the bladder neck area under the vaginal digital guidance.

[0017] Gittes and Loughlins[5] have further popularized the technique of Pereyra and demonstrated an advan-

tage of increased long-term efficacy by creating an autologous bolster with the transvaginal passage of a curved needle. As an alternative manner of creating an autologous bolster, the proposed modification described herein uses the suture passer disclosed herein, or a Stamey needle through a suprapubic approach to carry the suture through all of its vaginal passes. The full carriage of the suture by the suture passer needle offers the benefits of 1) improving accuracy and reproducibility by allowing palpation of the needle at each vaginal entry point in reference to the bladder neck and catheter, 2) potentially decreasing morbidity by reducing the risk of injury and/or irritation through inadvertent entry into any part of the urethra or bladder and 3) possibly contributing to long term efficacy by assuring that a full thickness layer of pubocervical fascia is captured. This technique permits the capture of a large lateral volume of pubocervical fascia similar in an area to that available for suturing in an open retropubic urethropexy.

[0018] Leach[4] has limited morbidity by decreasing post-operative pain and has potentially improved long-term efficacy with pubic fixation of the suspending sutures. However, the trochar needle passage through the pubic bone as described by Leach can be difficult through the limited exposure that is used with some forms of endoscopic bladder neck suspension. Other various forms of pubic bone fixation have also been described with transvaginal and open bladder neck suspension surgery[6,7,8]. To facilitate the anchoring of the suspensory suture to the pubic bone with minimal soft tissue dissection, the present inventor has used a new set of devices called the Mitek Anchor System. The latest generation of Mitek anchor, the G2, consists of a titanium body coupled to nickel-titanium arcs. These anchors have recently been used most commonly for tenodesis and ligamentous reconstruction of the shoulder and foot 9, 11.

[0019] In the present setting of bladder neck suspensions, the Mitek anchor with attached suture is passed into a hole drilled in the pubic bone. Care must be taken to assure that the hole has been drilled into the pubic bone and not inferiorly through the tendon of the adductor longus or superiorly through the rectus fascia over the surface of the pubis. Proper location of the drill and placement of the bone anchor in the bone is facilitated by a drill guide. Once the anchor is passed into the bone, the anchor's unique memory forces the arcs to spring open to their original shape and to engage in the cancellous portion of the pubic bone. The complication of infection with use of the anchor has not been noted, which may, in part, be due to the emphasis on broad spectrum antibiotics and sterile technique with use of video endoscopy, when possible.

[0020] Anchor pubic bone fixation in one study by the inventor herein was associated with a limitation of post-operative pain allowing the procedure to be performed on an outpatient basis in many of the patients. Pubic anchor fixation may limit suspending suture pull through at the level of the rectus fascia. Any assessment of resultant improvement of long term efficacy will require longer follow-up.

[0021] Certain specific embodiments of the devices of the present invention will follow, together with an example of the inventive bladder neck suspension procedure.

[0022] A suture passer is adapted for grasping and passing internal sutures to construct a supporting sling disclosed herein. The suture passer is particularly suited for use in connection with such surgery as the bladder suspension procedure, where sutures are required to be advanced and withdrawn without direct visualization and through relatively long distances. Alternatively, the suture passer may be used with other techniques such as Pereyra, Stamey and Gittes methods.

[0023] The suture passer enables the clinician to avoid accidental damage to the patient's internal structures and accidental needle sticks to himself and operating room personnel. The passive retraction of the needle point within the cannula, which will be discussed, facilitates the foregoing safety features, and secure capture of the suture material. The ability to advance the cannula with a blunt (retracted needle tip) end also facilitates internal suturing without direct visualization. Safe direct tactile feedback is provided along organ surfaces to localize placement of the suture. Referring to Figure 1, there is disclosed a suture passer 105 in accordance with one embodiment of the present invention.

[0024] In general, suture passer 105 comprises a handle 110, an axially movable probe 115, and a probe guide 125 having a suture channel 130. Details of suture channel 130 and related structures can be seen in the enlarged view in Figure 2.

[0025] Handle 110 serves both as a gripping area for the user and as a support structure for the suture passer 105. Handle 110 preferably comprises a hollow tubular body having proximal end wall 111 and distal end wall 112. Handle 110 is preferably of such a size to be easily gripped by a user. A handle 110 being at least approximately .75 inches (20 mm) in diameter and 4 inches (110 mm) in length has been found to work well. Preferably, handle 110 is provided with knurling or other surface texturing to produce a high friction gripping surface.

[0026] A support 135 is preferably mounted such that it extends from the distal end of the handle 110 to provide a mounting support for probe guide 125. The support 135 as illustrated is provided with a generally cylindrical proximal section 137 for engagement within the distal end of the handle 110 and a tapered distal section 139 for securing probe guide 125. The support 135 acts as a transition member from the handle 110 to support the probe guide 125.

[0027] The probe guide 125 comprises an elongated tubular member which is at its proximal end inserted

within or secured to the support 135. The probe guide 125 may be fixed to the support 135 in any variety of manners, including brazing, threading or others known in the art.

[0028] The probe guide 125 extends distally therefrom and is preferably within the range of from 15 cm to 20 cm (6 inches to 8 inches) in length and may be straight or curved. The length of probe guide 125 may vary, of course, depending on the exact intended procedure.

[0029] At its distal end, the probe guide 125 is provided with a smooth tapered engaging face 140. The distal extreme of tapered face 140 is slightly rounded or polished so that it can be pressed lightly against and swept along the surface of tissue such as the pubocervical fascia without cutting or traumatizing the tissue.

[0030] The probe guide 125 is preferably no more than about 2.5 mm (.1 inches) in diameter and is provided with at least one central lumen for acceptance of an axially movable probe 115. An elongate probe 115 is mounted within the handle 110 and extends through the support 135 and the probe guide 125. Probe 115 is preferably provided at its proximal end with a relatively large diameter body portion 116 adapted for reciprocal motion within tubular handle 110. Body portion 116 is preferably provided with a slightly smaller diameter recessed portion 117 for receiving a return spring 142 which biases the probe in the proximal direction. Alternatively, any of a variety of means can be utilized to provide a proximal bias on probe 115.

[0031] The length of body portion 116 is less than the axial length of the cavity within handle portion 110 so that the body portion 116 has an axial range of motion within the range of from about 2 mm to about 10 mm, and preferably about 3 mm (.12 inch). The proximal end wall 136 of support 135 which extends into the handle 110 acts as one limiting stop for distal travel of body 116. The distal surface of end wall 111 limits proximal travel of body 116. Spring 140 pushes against an annular shoulder 118 on body portion 116, biasing the probe 115 proximally.

[0032] The distal end of probe 115 is provided with a sharpened tip 120. Spring 142 normally biases tip 120 towards a first retracted position within the distal end of probe guide 125. Axial distal force on body portion 116 extends tip 120 into a second exposed position as illustrated in Figures 1 and 2. Although the probe 115 may be actuated in any number of ways, such as by use of a knob or button, it is presently preferred that a rotatable cam 122 be used.

[0033] The cam 122 is attached to a post 150 which extends proximally from the handle 110. The cam 120 is rotatably mounted about a pin 155 which extends in an axis perpendicular to the longitudinal axis of the probe 115. The proximal end of the body portion 116 has a rod 145 which extends proximally through an opening 147 in the proximal end wall 111 of the handle 110.

[0034] The cam 122 has at least a two position engaging surface which, when rotated into position, engages the rod 145 of the body 116. In a first position, the bias imposed by return spring 142 is overcome and the sharpened distal end 120 of probe 115 is extended outwardly from the probe guide 125. In a second engaged position, the distal end 120 remains within probe guide 125, but the suture lock is actuated as will be discussed. In a third position, the distal tip 125 is fully retracted within guide 125, and the suture lock is open such as for receiving or releasing a suture.

[0035] The cam 120 is preferably provided with an actuator portion 156 which extends radially outwardly and which may be used by the operator for rotating the cam 122.

[0036] A suture channel 130 is provided near the distal end of probe guide 125. Channel 130 cooperates with an annular or slotted recess 160 near the distal end of the probe 115. Suture channel 130 comprises an opening in the probe guide 125 which extends radially inwardly into the guide 125 and then generally axially along the guide 125 towards the distal end. The annular or slotted recess 160 in the probe 115 is located such that when the probe 115 is retracted to the proximal limit, the recess 160 and the opening in the channel 130 are aligned for receiving a suture therein.

[0037] At least a portion of the suture channel 130 extends generally axially along the guide 125 such that when a suture 165 is located in the recess 160 of the probe 115, the probe 115 may be extended to an intermediate, "locked" position, or to a distal position in which tip 120 is exposed outside of the probe guide 125. In this extended probe position and at all positions between the proximal and distal limits, the suture 165 is trapped within the recess 160 in the probe 115.

[0038] It is preferred that this instrument be manufactured from a sterilizable material having sufficient rigidity for its intended purpose.

[0039] Many acceptable materials are well known in the art, such as stainless steel for the needle and needle guide, and stainless steel or a plastic for the handle portion.

[0040] The suture passer 105 is operated first by rotating the cam 122 that engages the rod 145 and extends the probe end 120 distally of the probe guide 125. The passer 105 is then extended into a patient's body by gripping the handle 110 and pushing the free end of the probe guide 125 into the body and through the layers of tissue discussed in Example I, infra, and illustrated in Figs. 3a-4h. The cam 122 is then released and passively rotates to its neutral position 148 via action of spring 142 against the body 116 in turn pressing the rod 145 proximally against the cam ramp 149. The probe end 120 is thereby retracted into the probe guide 125 so that the suture passer can be manipulated without injury to surrounding tissue while keeping the suture 165 trapped in channel 130.

[0041] The suture passer 105 is then guided as discussed in Example I, to the desired capture point (see Fig. 4a) and the cam 122 rotated to a position in which

the suture channel 130 is aligned with the recess 160 of the probe 115. A length of suture 165 is transvaginally introduced at the introitus and digitally pressed against the outside of the probe guide 125 at a point proximal to the suture channel opening 130.

[0042] The suture 165 is then moved proximally until the suture 165 falls into the channel opening 130 and the annular or slotted recess 160 on the probe 115. The cam 122 is then operated so that rod 145 slides down cam ramp 149 under the bias of spring 142. At this time, the suture 165 is held securely within the channel 130, and distal tip 120 is retracted within guide 125. Preferably, channel 130 and recess 160 are dimensioned so that the suture 165 is slidably retained therein. The passer 105 may then be retracted from the body, thus drawing the suture 165 from inside the body. The construction of a bladder neck suspension web utilizing the suture passer will become apparent from the method disclosed in Example I, infra.

[0043] An alternate embodiment suture passer 805 is illustrated in FIGS. 6 and 6a. This passer 805 is very similar to the passer 105 described above, and therefore will not be redescribed in full detail here. This passer 805 is particularly suited and designed to be disposable. It is understood, however, that the description above, to the extent possible, applies to this embodiment of the passer 805 as well.

[0044] As illustrated, the passer 805 comprises a handle 810, an axially movable probe 815, and a probe guide 825 having a suture channel 830. The main difference between this passer 805 and that described above 105 is that the probe guide 825 of this embodiment 805 is slightly bowed. As illustrated, the guide 825 preferably has a diameter of approximately 2.4 mm, and is preferably approximately 178 mm long, and is bowed in one direction such that the free end of the guide 825 is located off of the axis of the passer 805.

[0045] Further, an actuator lever 822 is used to actuate the probe 815 instead of the cam 122 described in conjunction with passer 105. This lever 822 is similar to the cam 122 described above, except that it includes a protruding engaging portion 890 which extends for engagement by a thumb or hand. Preferably, the lever 822 is rotatably mounted about a pin (not shown) which extends in an axis perpendicular to the longitudinal axis of the probe 815. The lever 822 is directly connected to a rod (not shown) which is located on the proximal end of the probe 815, similar to that described above.

[0046] The lever 822 allows the user to actuate the probe 815 by manipulating the engaging portion 890. When it is desired to extend the probe 815, the lever 822 is positioned such that the engaging portion 890 is in a nearly upright position, or perpendicular to the axis of the probe 805. Alternatively, when it is desired to retract the probe 815, the engaging portion 890 of the lever 822 is pressed rearwardly with respect to the probe 822 until the desired amount of probe 815 retraction is achieved, or until the movement of the probe 815 is stopped by the proximal end of the probe 815 contacting the inside end of the housing 810.

[0047] In order for this passer 805 to be disposable, it is desired that its components, (except for the guide 825, probe 815, and an internal spring, which are preferably manufactured of stainless steel) be made of a suitable thermoplastic. In particular, the thermoplastic Cycolac 2679F made by General Electric Plastics has been found suitable, which is Acrylonitrile Butadiene Styrene (ABS).

[0048] Use of the passer 805 is similar to that described above in conjunction with passer 105, and therefore will not be described again here.

EXAMPLE I

[0049] A group of patients are prepared as follows. All patients receive gentamacin and ampicillin preoperatively unless an allergy exists. Anaesthesia is regionally or generally applied. A surgical assistant is not used. The patients are placed in the lithotomy position. Preparation emphasises isolation of the anus with a stapled towel or plastic drape. A Foley catheter is passed. Two separated 2.5 cm (1 inch) transverse incisions are made over the pubic bone (Fig. 3) and dissection is carried down to the area of the rectus fascia. Beginning on the right side, the wound is stretched cephalad to allow the vertical passage of a suture passer of the type illustrated in Figs. 1 and 2 through the rectus fascia with the probe tip fully exposed (Fig. 4a). Distal advancement of the suture passer is accomplished with the needle (probe) tip proximally retracted within the probe guide. The suture passer is acutely angled into the abdomen so that the point rests on the underside of the pubic periosteum (Fig. 4b). while maintaining contact with the underside of the pubis, the suture passer with the probe tip retracted is thereafter passed distally toward the introitus. At the completion of this distal passage, the suture passer can be palpated through the introitus to the right of the urethra (Fig. 4c). The distal end tip of the suture passer is withdrawn from the surface of puboure-thral ligament and gently swept along the pubocervical fascia to the area of the bladder neck (Fig. 4d) under the guidance of a finger within the vagina. Palpation through the vagina may be safely preformed to assist in localization of suture passer tip.

[0050] The probe tip is then distally extended. The suture passer is then passed through the pubocervical fascia and vaginal mucosa at point 1 (Fig. 5a). The probe is then retracted maximally to the unlocked position to allow a number 1 polypropylene suture to be manually placed into the suture channel. The probe is moved distally to lock the suture therein. The suture passer is thereafter withdrawn through the pubic wound (Fig. 5b) and the suture is released from the suture channel by manually retracting the probe.

[0051] The suture passer with the probe tip extended is then reintroduced through the rectus fascia 2 cm lat-

eral to the initial passage and through the vaginal mucosa at point 2 (Fig. 5c) using the same passage technique described above Fig. 4a-d). The vaginal end of the suture is then placed into the open end of the suture channel and locked. The suture passer is then withdrawn into the retropubic space (Fig. 5d) and then advanced to point 3 where it is passed through the vaginal mucosa as with point 1 and 2 and passed out of to the introitus (Fig. 5e).

[0052] The suture is then removed from the suture passer by maximally retracting the probe tip to the "unlocked" position to align the suture channel and opening in the probe guide, and the suture passer is once again withdrawn into the retropubic space (Fig. 5f). The probe tip is then extended and the suture passer is pushed through the vaginal mucosa at point 4 (Fig. 5g). The vaginal end of the suture is then placed into the unlocked suture channel and locked into place, and pulled up through the pubic wound. An attempt is made with the 4 entry points through the pubocervical fascia to maximize 1) their separation (approximately 2 cm apart), and 2) their lateralization from the bladder neck and urethra (approximately 2 cm away).

[0053] The identical procedure is performed on the left side. Direct or video cystoscopic confirmation of suture position is performed on the left side. Direct or video cystoscopic confirmation of suture position is performed with special attention to avoid handling the contaminated eyepiece of the cystoscope when video cystoscopy is done.

[0054] The Mitek G2 Anchor System (Mitek Surgical Products. Inc., Northwood, Massachusetts) is then used in all patients for pubic bone fixation of the suspensory sutures. Drill sites are located by placing a drill guide 25 over the pubic bone and extending the bone probes distally until both bone probes have made contact with the pubic bone. A 2.5 mm drill bit is advanced through the drill guide to produce two holes drilled into the pubic bone approximately 2 cm lateral to the symphysis. One anchor for each side (2 per patient) is loaded into the drill guide channel and advanced into its hole before removing the drill guide after drilling. Traction is placed on the sutures to assure adequate fixation of the anchors.

[0055] The sutures on each side are then tied down with sufficient tension so as to develop a gentle elevation and cradle-like support of the bladder neck. Tension is regulated by tying the sutures across a suture tensioner and thereafter removing the tensioner.

[0056] The patients are post-operatively treated as follows. The wounds are irrigated with a bacitracine solution. The wound edges and the rectus fascia at the suture entry points are infiltrated with bupivacaine. A Foley catheter may be placed. Alternatively a suprapubic tube may be placed in patients with dexterity problems or aversion to learning intermittent catheterization.

[0057] Following surgery, patients are given either ciprofloxacine or ofloxacine for 10 days. The patients' Foley catheters are removed one week following surgery. The patients perform intermittent catheterization as necessary until the post-void residuals are less than 75 cc on two consecutive catheterizations. The patients with suprapubic tubes generally begin voiding trials at 4 days following surgery. The suprapubic tubes are removed when the post-void residuals are less than 75 cc following two consecutive urinations.

EXAMPLE II

[0058] Another procedure involves using one or more sutures, the suture supports, the suture passer and anchors, to suspend the bladder neck. The patient is first prepared by installing a pubic drape. Once the drape is in place, a small 2.5 cm (1 inch) transverse incision is made over the pubic bone. The tip 120 of the suture passer 105 is passed through the rectus fascia and then sharply angled onto the abdomen so that the point rested on the underside of the pubic periosteum. The tip 120 of the suture passer 105, while maintaining contact with the underside of the pubis, is thereafter passed distally to the pubourethral ligament and gently swept along the pubocervical fascia to the area of the bladder neck under guidance of a finger in the vagina. The suture passer 105 is then passed through the pubocervical fascia and vaginal mucosa into the vagina.

[0059] A suture is then tied off to a suture support 450 on one end and the other end is then captured by a suture capturing device, such as in the suture channel 130 of the suture passer 105 as previously described. The suture is then withdrawn upward through the rectus fascia and out through the incision. In this manner, the suture is easily passed through the tissue of the patient with exact placement. The suture should be pulled slightly taut. At this time the suture support will be pulled against the vaginal wall. A Mitek anchor is then used to fix the suture to the bone. This is accomplished by one of the methods described above for placing the anchors.

[0060] Although this invention has been described in terms of certain preferred embodiments, other embodiments that are apparent to those of ordinary skill in the art in view of the foregoing are also within the scope of this invention as defined by reference to the appended claims.

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Claims

1. A suture passer adapted for releasably retaining a suture, comprising:

   a handle (110, 810);

   an elongate tubular probe guide (125, 825) extending in a distal direction from the handle (110, 810);

   an elongate pointed probe (115, 815) axially movably disposed within the tubular probe guide (125, 825) to facilitate penetration of tissue, the probe having a recess (160), characterized in that

   an opening (130, 830) is provided on the tubular probe guide (125, 825) for receiving a suture, said opening (130, 830) extending radially inwardly into said probe guide (125, 825) and then generally axially along said probe guide (125, 825) towards the distal end of the probe guide (125, 825),
   wherein the probe (115, 815) is axially movable with respect to the probe guide (125, 825) between a first position in which the recess (160) is aligned with the opening (130, 830) for receiving a suture therein, and a second position wherein the recess (160) is out of alignment with the opening (130, 830) to trap a suture within the recess.

2. A suture passer as in Claim 1, further comprising a third position so that in a first position the recess (160) is aligned with the opening (130, 830) for receiving a suture and the distal tip (120) of the probe (115, 815) is retracted within the probe guide (125, 825); in a second position the recess (160) is out of alignment with the opening (130, 830) and the distal tip (120) of the probe (115, 815) is retracted; and in a third position the recess (160) is out of alignment with the opening (130, 830) and the distal tip (120) of the probe is exposed.

3. A suture passer as in Claim 2, further comprising a control (122, 822) on the handle (110, 810) for selectively positioning the probe (115, 815) in any desired one of the three positions.

4. A suture passer as in Claim 3, further comprising an axially movable actuator rod (145) extending proximally from the pointed probe (115, 815).

5. A suture passer as in Claim 4, wherein the control comprises a rotatable cam (122) having a contoured engagement surface (149) for engaging the actuator rod (145) and holds the actuator rod in a stable position.

6. A suture passer as in any one of Claims 1 to 5, further comprising a spring (142) for biasing the probe (115, 815) in the proximal direction.

7. A suture passer as in Claim 6, wherein the engagement surface comprises a ramp (149) which cooperates with the actuator rod (145) and the proximal bias on the pointed probe (115, 815) so that the distal tip of the pointed probe is normally retracted within the distal end of the probe guide, and distally extended beyond the probe guide only during manual manipulation of the control.

8. A suture passer as in any one of the Claims 3 to 7, further comprising an indicium on the control for indicating the axial position of the pointed probe (115, 815).

9. A suture passer as in Claim 8, wherein the indicium comprises the rotational position of the cam (122).

10. A suture passer as in any one of the Claims 1 to 9, wherein said recess (160) comprises an annular or

slotted recess extending radially inwardly about the periphery of the probe (115, 815).

11. A suture passer as in any one of Claims 1 to 10, wherein the distal end of the probe guide (125, 825) is provided with a blunt atraumatic tip (140) which allows tactile positioning digitally.

12. A suture passer as in any one of the Claims 1 to 11, wherein said elongate tubular probe guide (125, 825) and said elongate pointed probe (115, 815) are curved.

13. A suture passer as in any one of the Claims 1 to 12, further comprising a suture extending through said recess (160) on said probe (115, 815).

14. A suture passer as in any one of the Claims 1 to 13, wherein in the second position the recess (160) is positioned distal to the portion of the opening (130, 830) which extends radially inwardly.

Patentansprüche

1. Fadenführer, angepaßt für das lösbare Festhalten eines Fadens, mit:

   einem Handgriff (110, 810);
   einer langgestreckten rohrförmigen Sondenführung (110, 810);
   einer langgestreckten spitzen Sonde (115, 815), die axial beweglich innerhalb der rohrförmigen Sondenführung (125, 825) angeordnet ist, um das Durchdringen von Gewebe zu erleichtern, wobei die Probe eine Aussparung (160) aufweist,
   dadurch gekennzeichnet, daß
   eine Öffnung (130, 830) an der rohrförmigen Sondenführung (125, 825) für die Aufnahme eines Fadens vorgesehen ist, wobei sich die Öffnung (130, 830) radial nach innen in die Sondenführung (125, 825) hinein erstreckt und dann im allgemeinen axial entlang der Sondenführung (125, 825) zu dem distalen Ende der Sondenführung (125, 825) hin erstreckt,
   wobei die Sonde (115, 815) in bezug auf die Sondenführung (125, 825) zwischen einer ersten Stellung, in welcher die Aussparung (160) zu der Öffnung (130, 830) für die Aufnahme eines Fadens darin ausgerichtet ist, und einer zweiten Stellung bewegbar ist, in welcher die Aussparung (160) nicht mehr zu der Öffnung (130, 830) ausgerichtet ist, um einen Faden innerhalb der Aussparung einzuschließen.

2. Fadenführer nach Anspruch 1, welcher ferner eine dritte Stellung aufweist, so daß in einer ersten Stellung die Aussparung (160) zu der Öffnung (130, 830) für die Aufnahme eines Fadens ausgerichtet und die distale Spitze (120) der Sonde (115, 815) in die Sondenführung (125, 825) zurückgezogen ist; in einer zweiten Stellung die Aussparung (160) nicht mehr zu der Öffnung (130, 830) ausgerichtet ist und die distale Spitze (120) der Sonde (115, 815) zurückgezogen ist; und in einer dritten Stellung die Aussparung (160) nicht mehr zu der Öffnung (130, 830) ausgerichtet ist und die distale Spitze (120) der Sonde offenliegt.

3. Fadenführer nach Anspruch 2, ferner mit einer Steuerungseinrichtung (122, 822) an dem Handgriff (110, 810) zum selektiven Positionieren der Sonde (115, 815) in jeder gewünschten von den drei Stellungen.

4. Fadenführer nach Anspruch 3, ferner mit einem axial beweglichen Betätigungsstab (145) der sich proximal von der spitzen Sonde (115, 815) weg erstreckt.

5. Fadenführer nach Anspruch 4, wobei die Steuereinrichtung eine drehbare Nocke (122) mit einer profilierten Eingriffsoberfläche (149) für einen Eingriff mit dem Betätigungsstab (145) aufweist, und den Betätigungsstab in einer stabilen Position hält.

6. Fadenführer nach einem der Ansprüche 1 bis 5, ferner mit einer Feder (142) zum Vorpannen der Sonde (115, 815) in der proximalen Richtung.

7. Fadenführer nach Anspruch 6, wobei die Eingriffsoberfläche eine Rampe (149) aufweist, welche mit dem Betätigungsstab (145) und der proximalen Vorspannung auf die spitze Sonde (115, 815) so zusammenwirkt, daß die distale Spitze der spitzen Sonde normalerweise in das distale Ende der Sondenführung zurückgezogen ist, und sich distal über die Sondenführung hinaus nur während der manuellen Betätigung der Steuerungseinrichtung erstreckt.

8. Fadenführer nach einem der Ansprüche 3 bis 7, ferner mit einem Anzeigeelement auf der Steuerungseinrichtung zur Anzeige der axialen Stellung der spitzen Sonde (115, 815).

9. Fadenführer nach Anspruch 8, wobei das Anzeigeelement die Drehstellung der Nocke (122) mit umfaßt.

10. Fadenführer nach einem der Ansprüche 1 bis 9, wobei die Aussparung (160) eine ringförmige oder schlitzförmige Aussparung aufweist, die sich radial nach innen gerichtet um den Umfang der Sonde (115, 815) herum erstreckt.

11. Fadenführer nach einem der Ansprüche 1 bis 10, wobei das distale Ende der Sondenfuhrung (125, 825) mit einer stumpfen atraumatischen Spitze (140) versehen ist, welche eine digital tastbare Positionierung erlaubt.

12. Fadenführer nach einem der Ansprüche 1 bis 11, wobei die langgestreckte rohrförmige Sondenführung (125, 825) und die langgestreckte spitze Sonde (115, 815) gekrümmt sind.

13. Fadenführer nach einem der Ansprüche 1 bis 12, ferner mit einem durch die Aussparung (160) auf der Sonde (115, 815) sich hindurch erstreckenden Faden.

14. Fadenführer nach einem der Ansprüche 1 bis 13, wobei in der zweiten Stellung die Aussparung (160) distal zu dem Abschnitt der Öffnung (130, 830) ausgerichtet ist, welcher sich radial nach innen erstreckt.

Revendications

1. Passe-fil pour suture adapté à retenir provisoirement une suture, comprenant :

   une poignée (110,810) ;
   un guide de sonde (125,825) tubulaire et allongé, s'étendant dans une direction distale depuis la poignée (110,810) ;
   une sonde (115,815) allongée et pointue, disposée, axialement et mobile, dans le guide de sonde tubulaire (125,825) pour faciliter la pénétration des tissus, la sonde ayant un creux (160),
   caractérisé en ce que :
   une ouverture (130,830) est prévue dans le guide de sonde tubulaire (125,825) pour recevoir une suture, ladite ouverture (130,830) s'étendant radialement vers l'intérieur dans ledit guide de sonde (125,825), puis généralement axialement le long dudit guide de sonde (125,825) en direction de l'extrémité distale du guide de sonde (125,825),
   et en ce que la sonde (115,815) est mobile axialement par rapport au guide de sonde (125,825) entre une première position dans laquelle le creux (160) est aligné avec l'ouverture (130,830) pour y recevoir une suture, et une seconde position dans laquelle le creux (160) est hors d'alignement avec l'ouverture (130,830) pour piéger une suture dans ledit creux.

2. Passe-fil pour suture selon la revendication 1, comprenant en outre une troisième position de telle sorte que, dans une première position, le creux (160) est aligné avec l'ouverture (130,830) pour recevoir une suture et la pointe distale (120) de la sonde (115,815) est rétractée à l'intérieur du guide de sonde (125,825) ; dans une seconde position, le creux (160) est hors d'alignement avec l'ouverture (130,830) et la pointe distale (120) de la sonde (115,815) est rétractée ; et, dans une troisième position le creux (160) est hors d'alignement avec l'ouverture (130,830) et la pointe distale (120) de la sonde est à découvert.

3. Passe-fil pour suture selon la revendication 2, comprenant en outre une commande (122,822) sur la poignée (110,810) pour positionner sélectivement la sonde (115,815) dans l'une quelconque, voulue, des trois positions.

4. Passe-fil pour suture selon la revendication 3, comprenant en outre une tige de piston (145) mobile axialement s'étendant à proximité de la sonde pointue (115,815).

5. Passe-fil pour suture selon la revendication 4, dans laquelle la commande comprend une came rotative (122) ayant une surface de venue en prise profilée (149) pour venir en prise avec la tige de piston (145) et maintenir la tige de piston (145) dans une position stable.

6. Passe-fil pour suture selon l'une quelconque des revendications 1 à 5, comprenant en outre un ressort (142) pour solliciter la sonde (115,815) dans la direction proximale.

7. Passe-fil pour suture selon la revendication 6, dans laquelle la surface de venue en prise comprend une rampe (149) qui coopère avec la tige de piston (145) et la sollicitation proximale s'exerçant sur la sonde pointue (115,815) de telle sorte que la pointe distale de la sonde pointue est normalement rétractée dans l'extrémité distale du guide de sonde, et qu'elle ne se projette distalement au-delà du guide de sonde que pendant la manipulation manuelle de la commande.

8. Passe-fil pour suture selon l'une quelconque des revendications 3 à 7, comprenant en outre un repère sur la commande pour indiquer la position axiale de la sonde pointue (115,815).

9. Passe-fil pour suture selon la revendication 8, dans lequel le repère indique la position en rotation de la came (122).

10. Passe-fil pour suture selon l'une quelconque des revendications 1 à 9, dans lequel ledit creux (160) comprend un creux annulaire ou rainé s'étendant radialement vers l'intérieur autour de la périphérie

de la sonde (115,815).

11. Passe-fil pour suture selon l'une quelconque des revendications 1 à 10, dans lequel l'extrémité distale du guide de sonde (125,825) est pourvue d'une pointe émoussée atraumatique (140) qui permet un positionnement tactile.

12. Passe-fil pour suture selon l'une quelconque des revendications 1 à 11, dans lequel ledit guide de sonde (125,825) tubulaire et allongé et ladite sonde (115,815) pointue et allongée sont courbes.

13. Passe-fil pour suture selon l'une quelconque des revendications 1 à 12, comprenant en outre une suture s'étendant au travers dudit creux (160) sur ladite sonde (115,815).

14. Passe-fil pour suture selon l'une quelconque des revendications 1 à 13, dans lequel, dans la seconde position, le creux (160) occupe une position distale par rapport à la portion de l'ouverture (130,830) qui s'étend radialement vers l'intérieur.

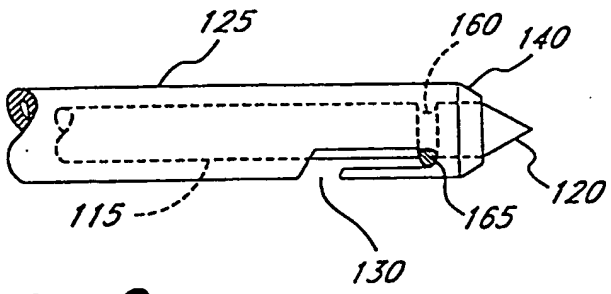
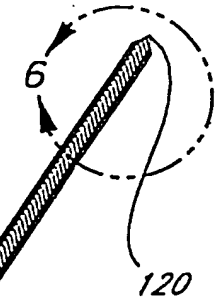

125
160
140
120
115
165
130

FIG. 2


6
120

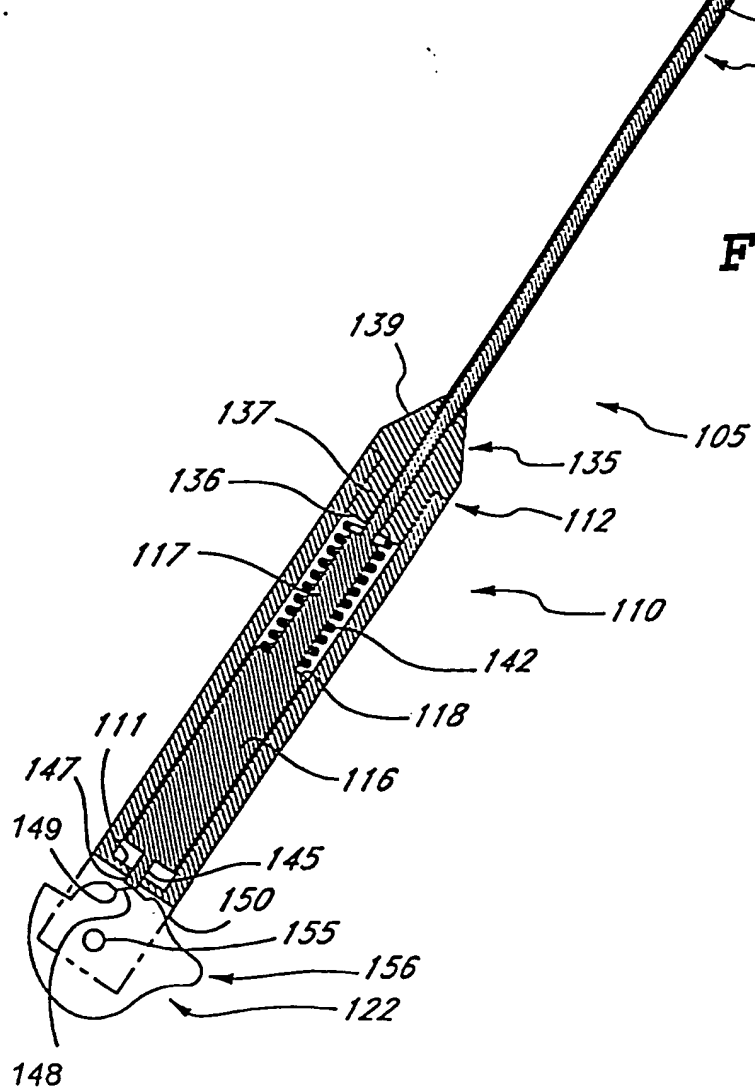

115
125
139
137
105
135
136
112
117
110
142
118
111
116
147
149
145
150
155
156
122
148

FIG. 1

FIG. 3

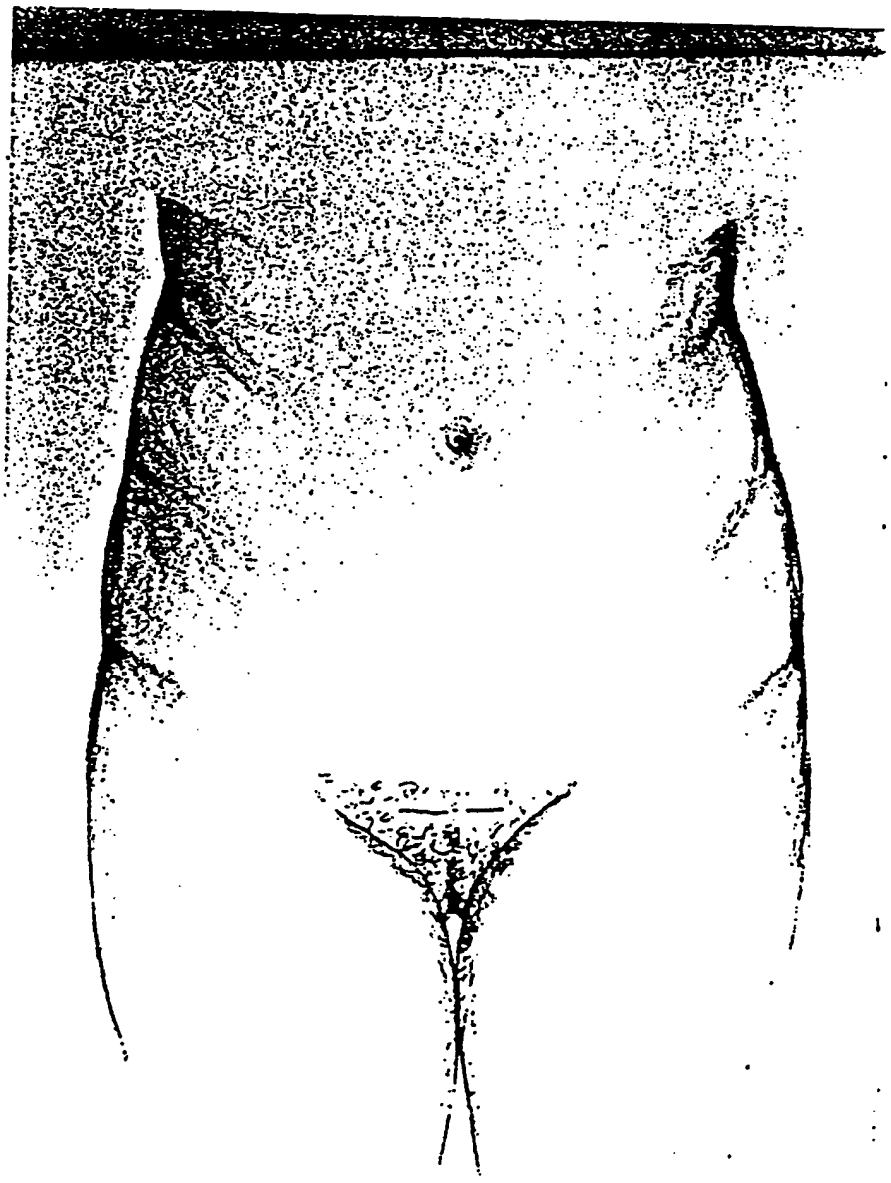


FIG. 4A

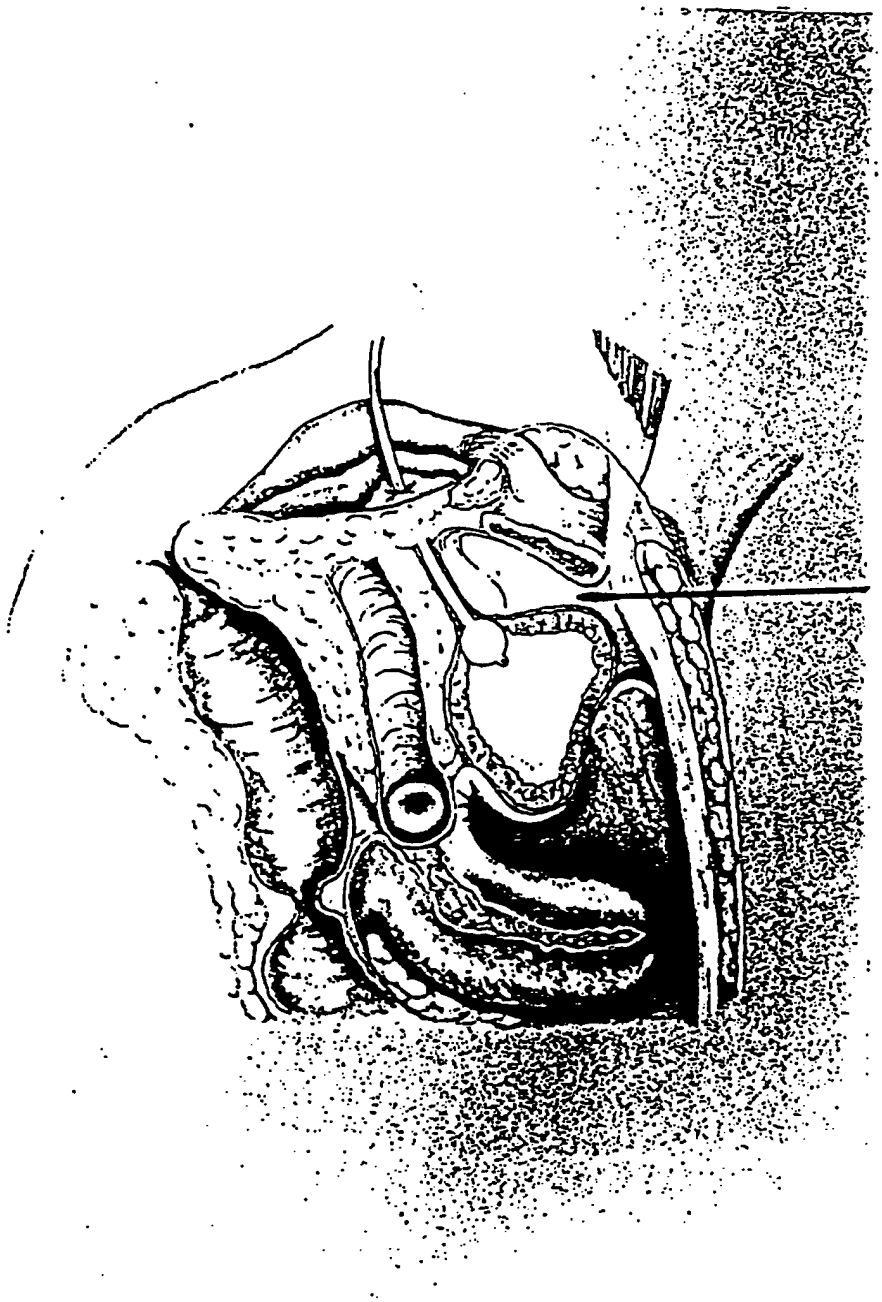


FIG. 4B

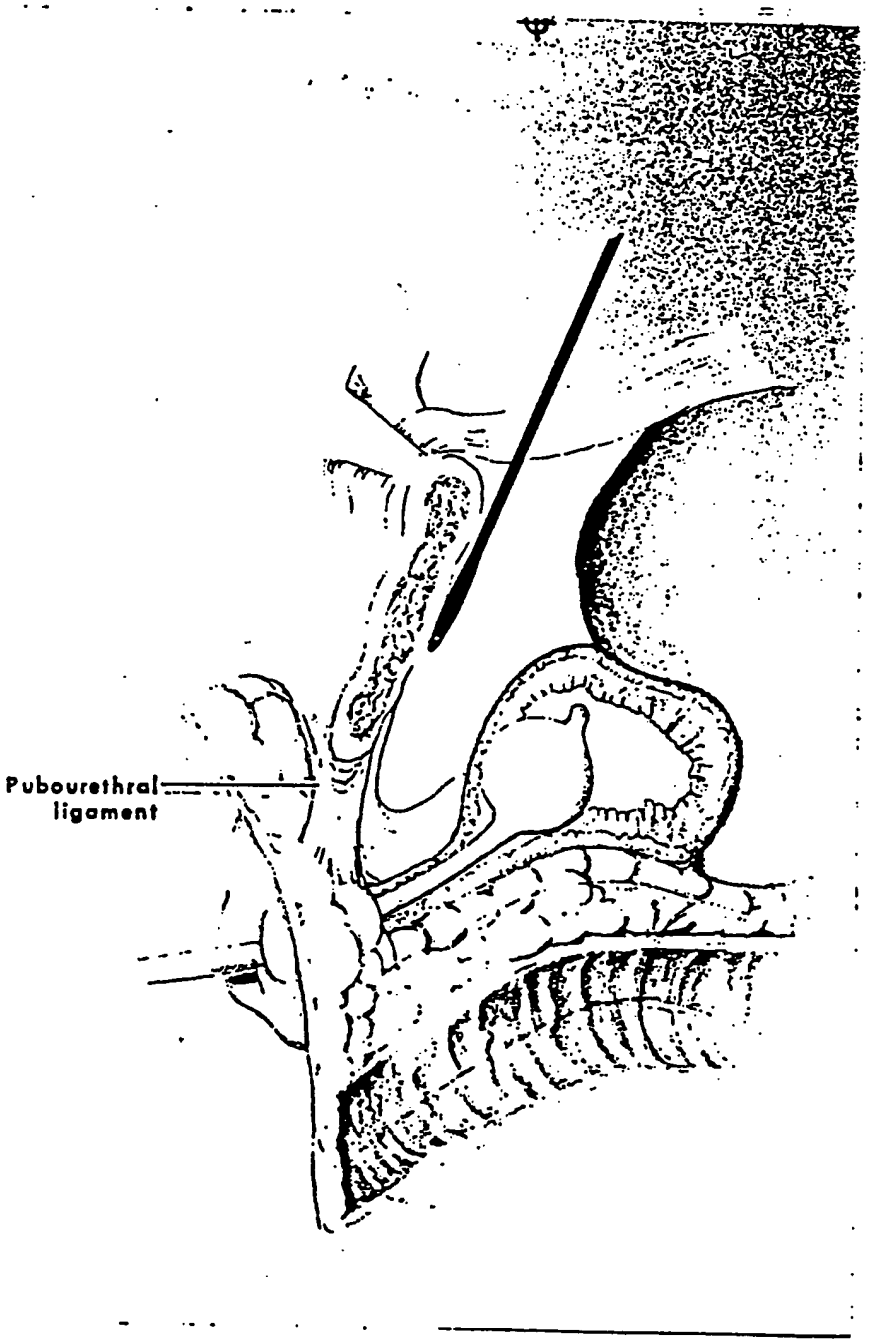


FIG. 4C

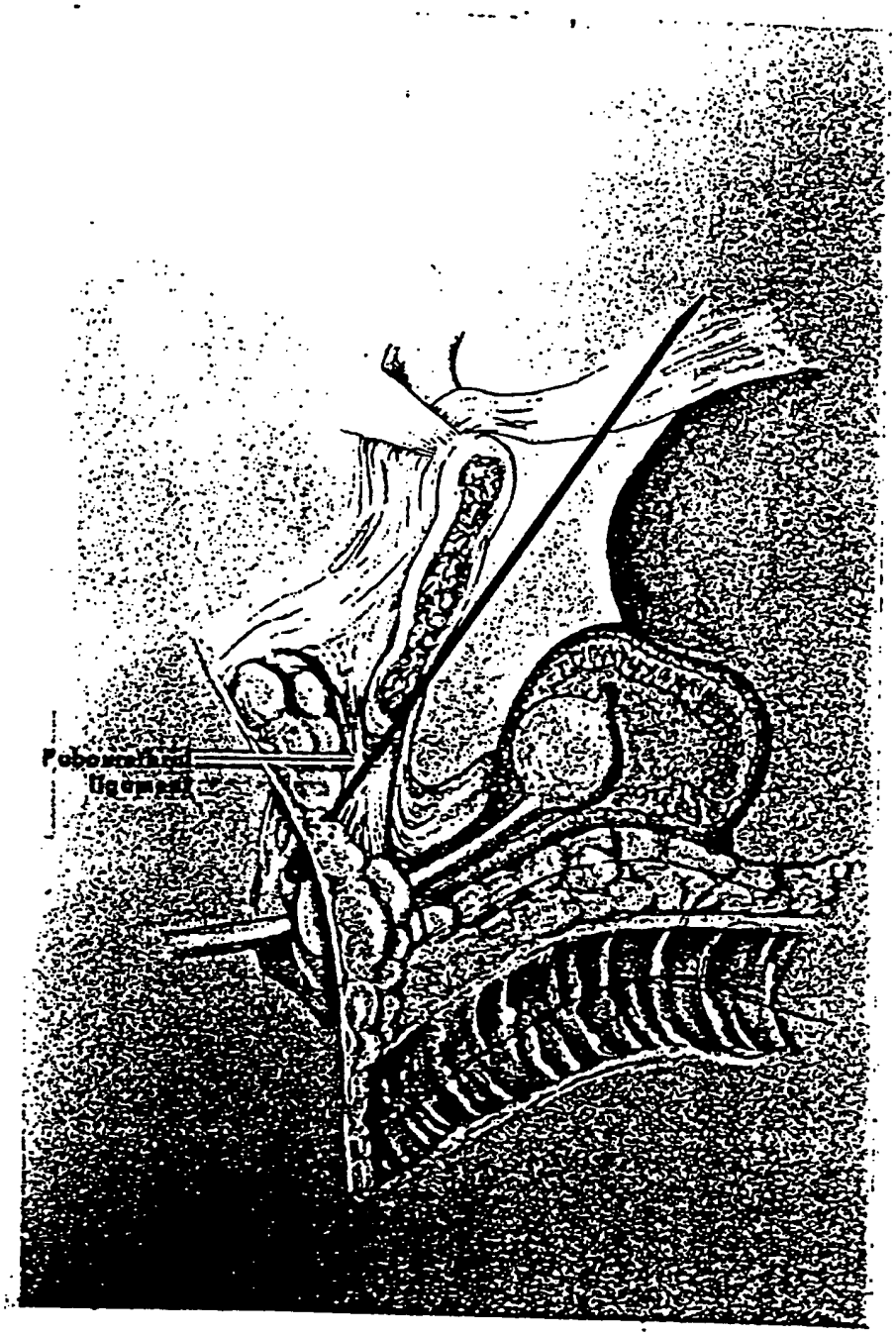


FIG. 4D

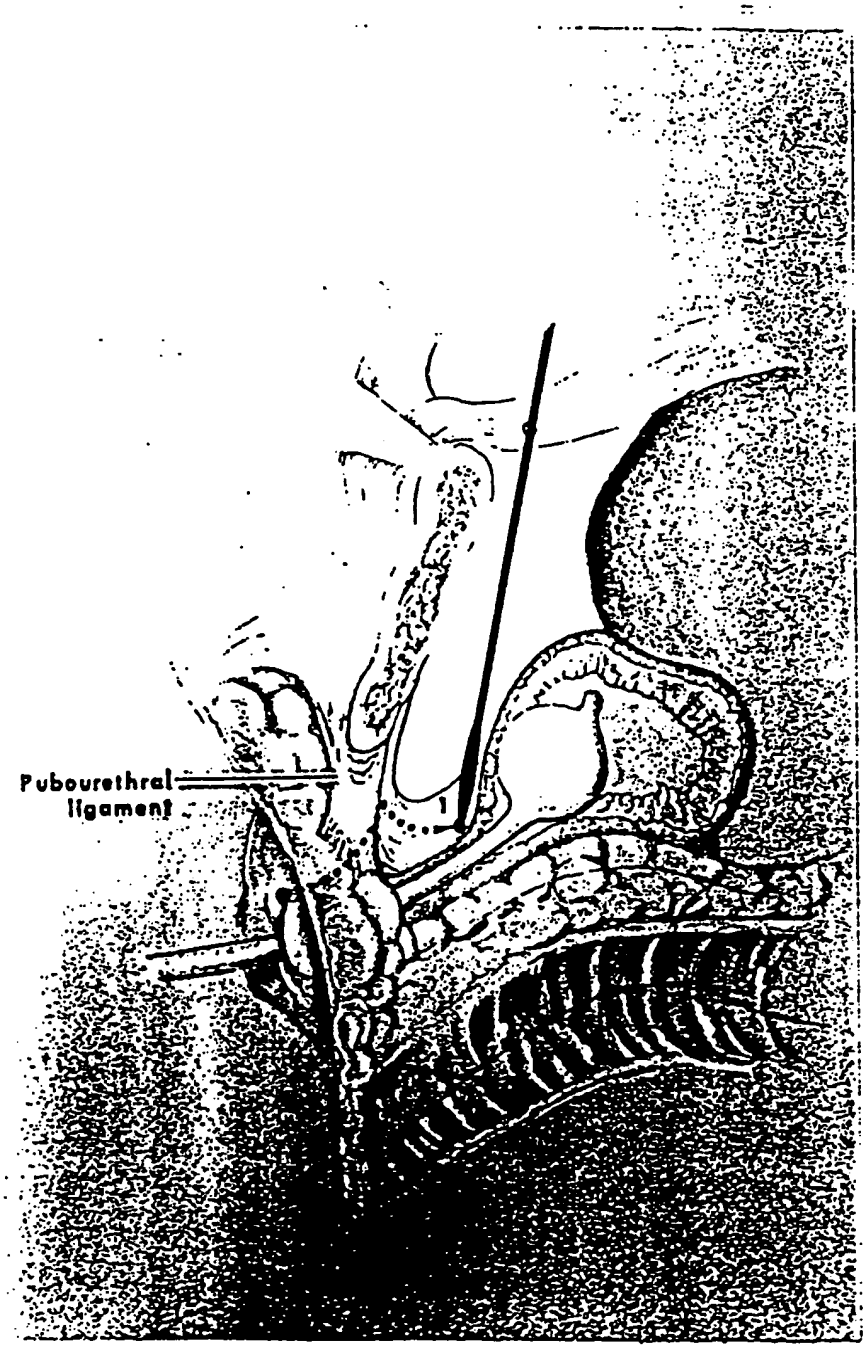


FIG. 5A

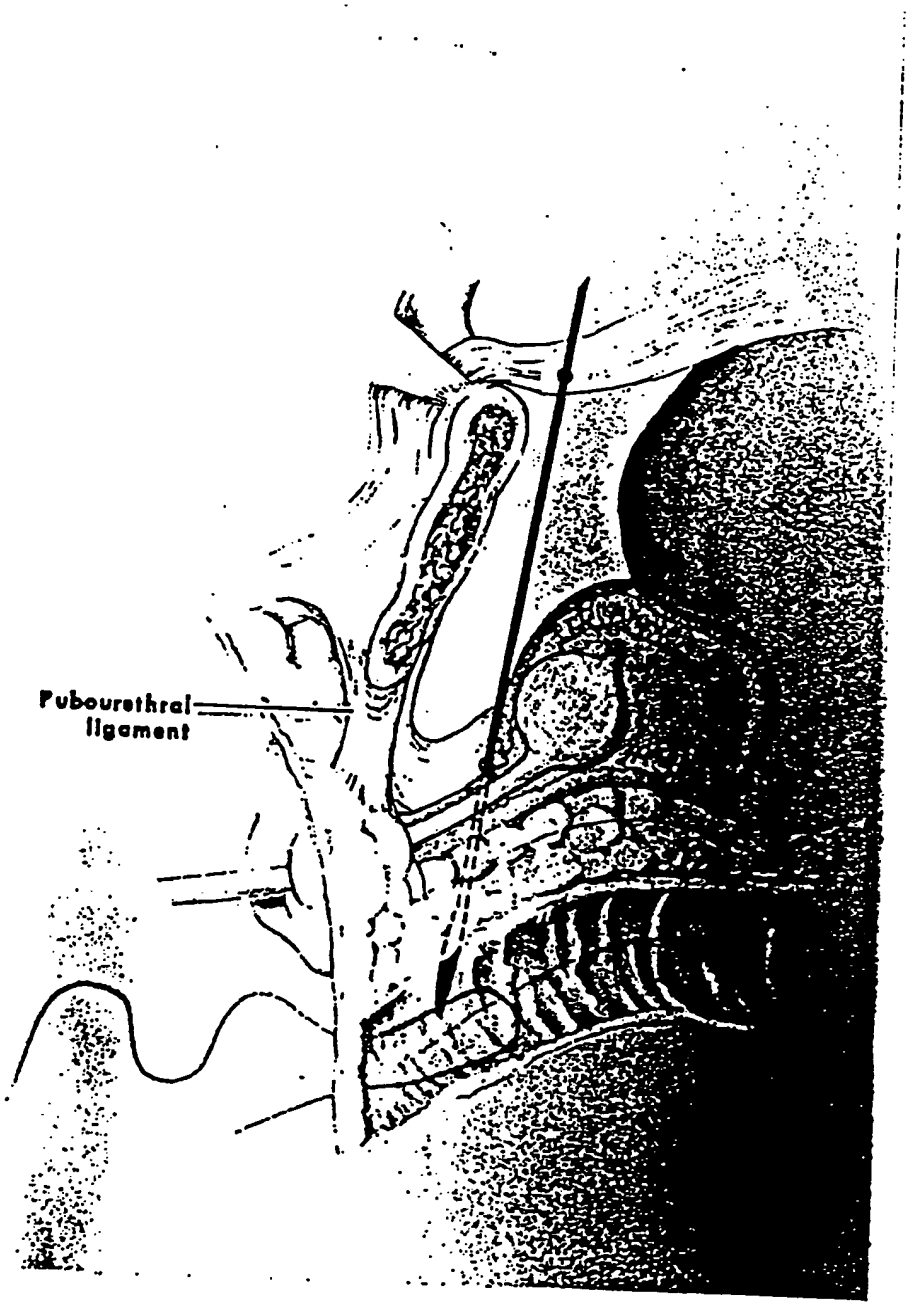


FIG. 5B

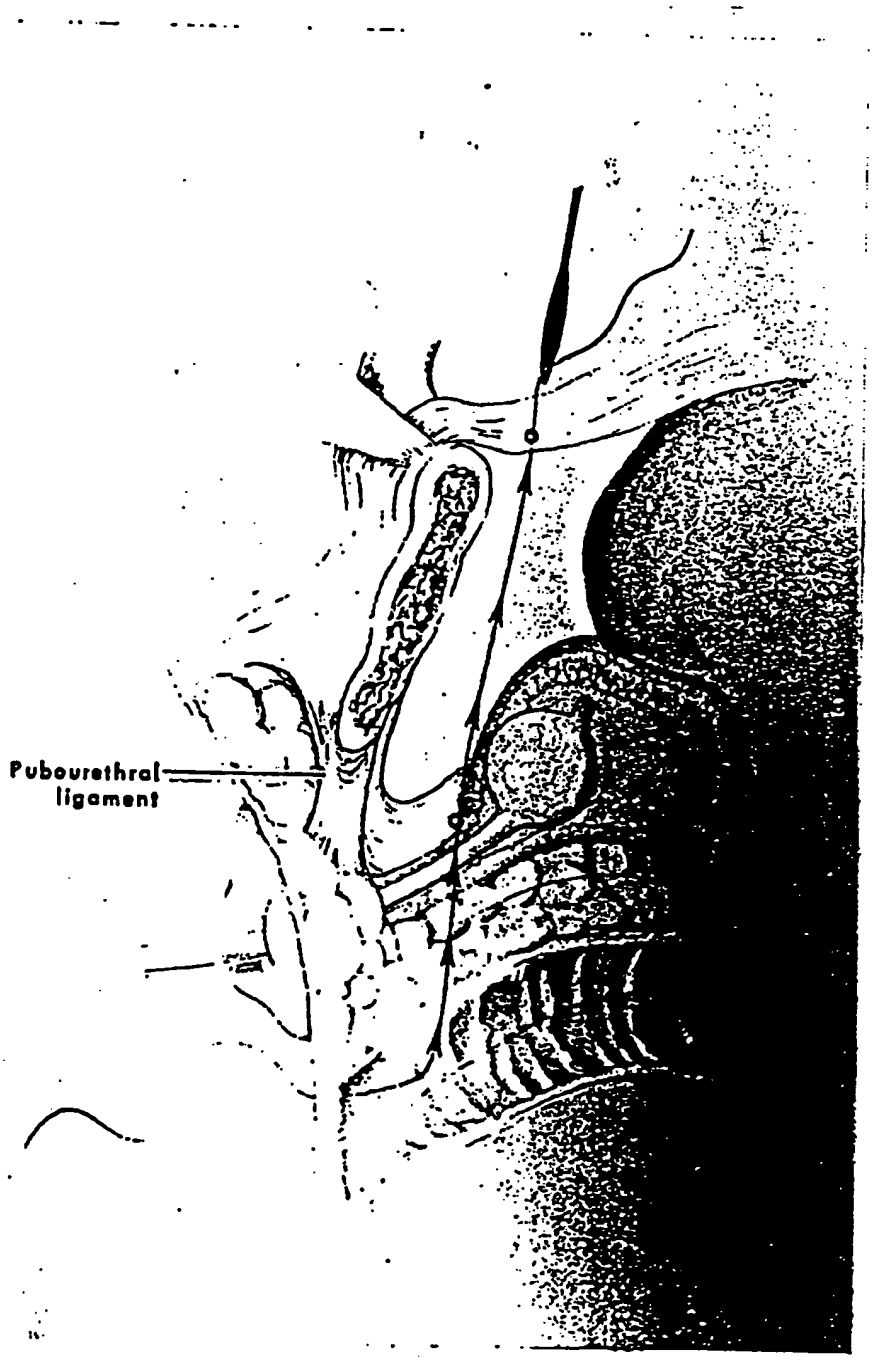


FIG. 5C

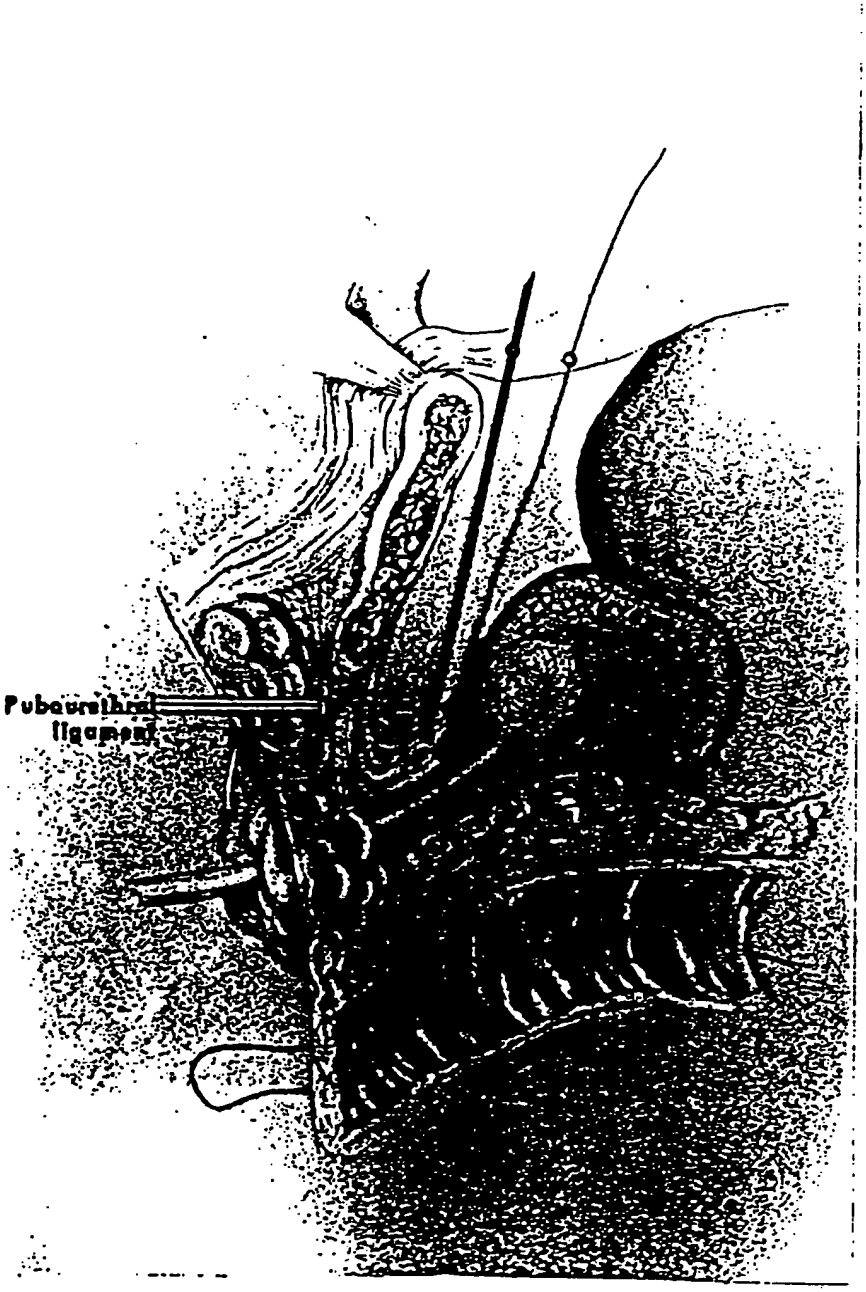


FIG. 5D

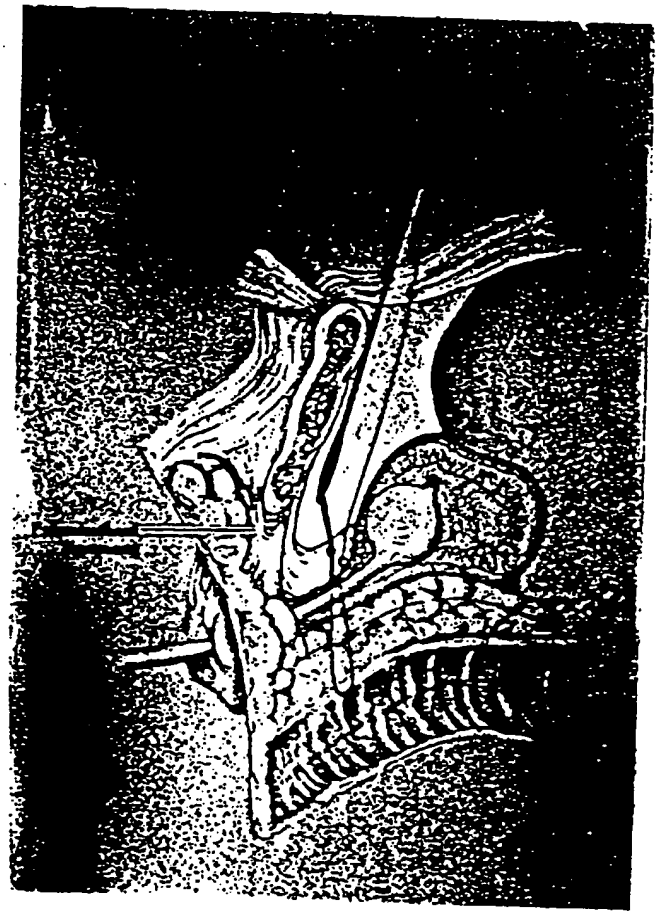


FIG. 5E

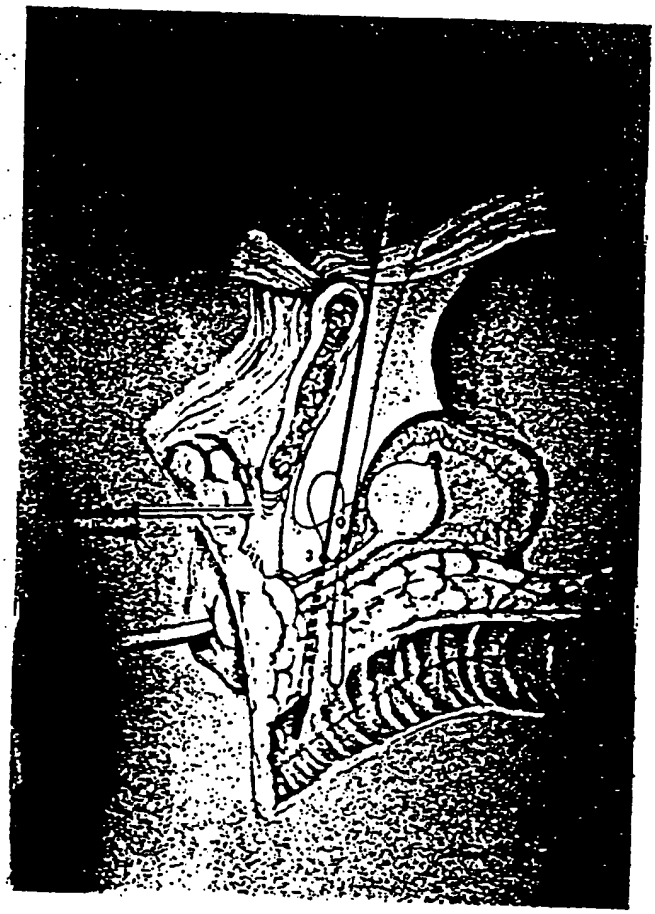


FIG. 5F

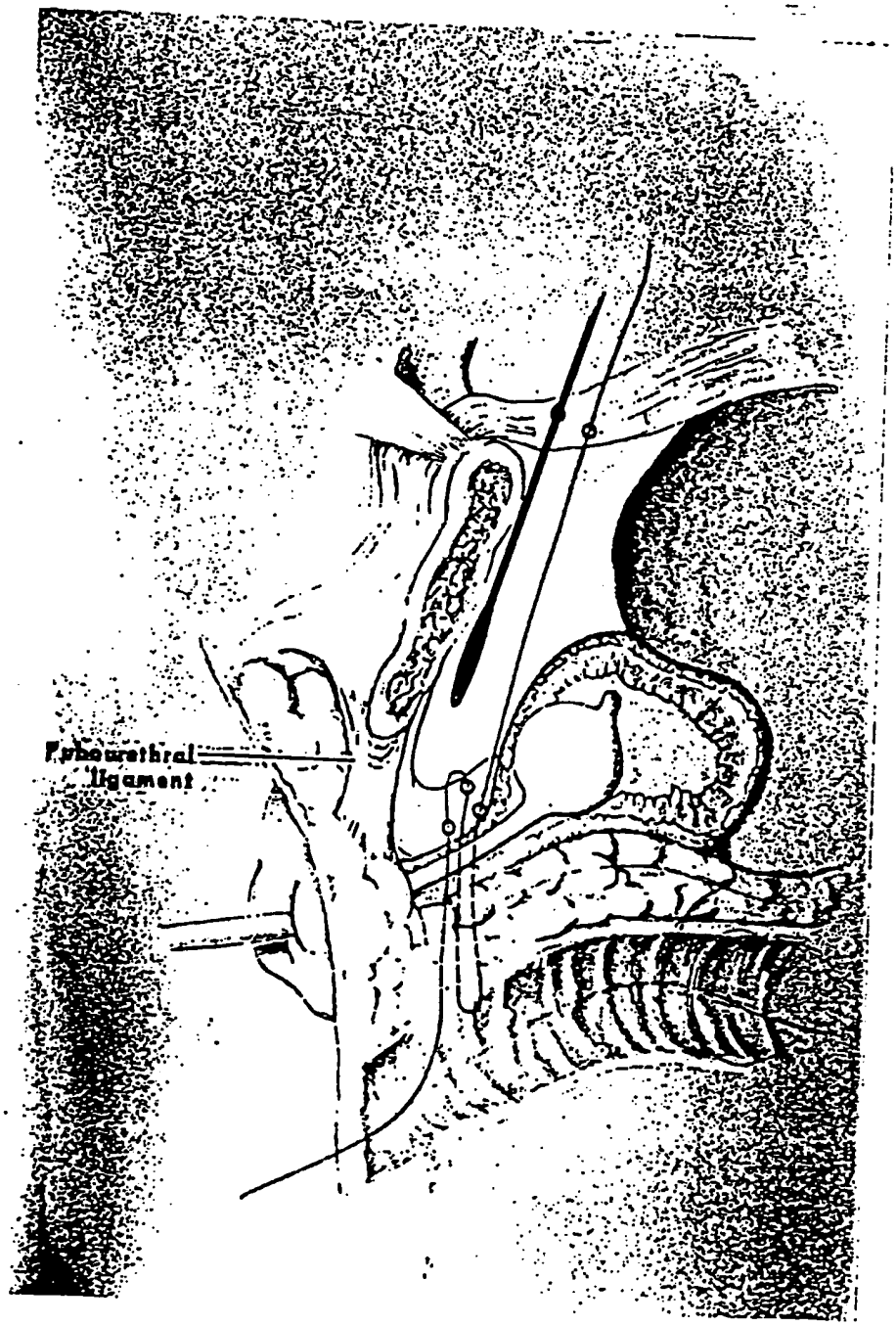


FIG. 5G

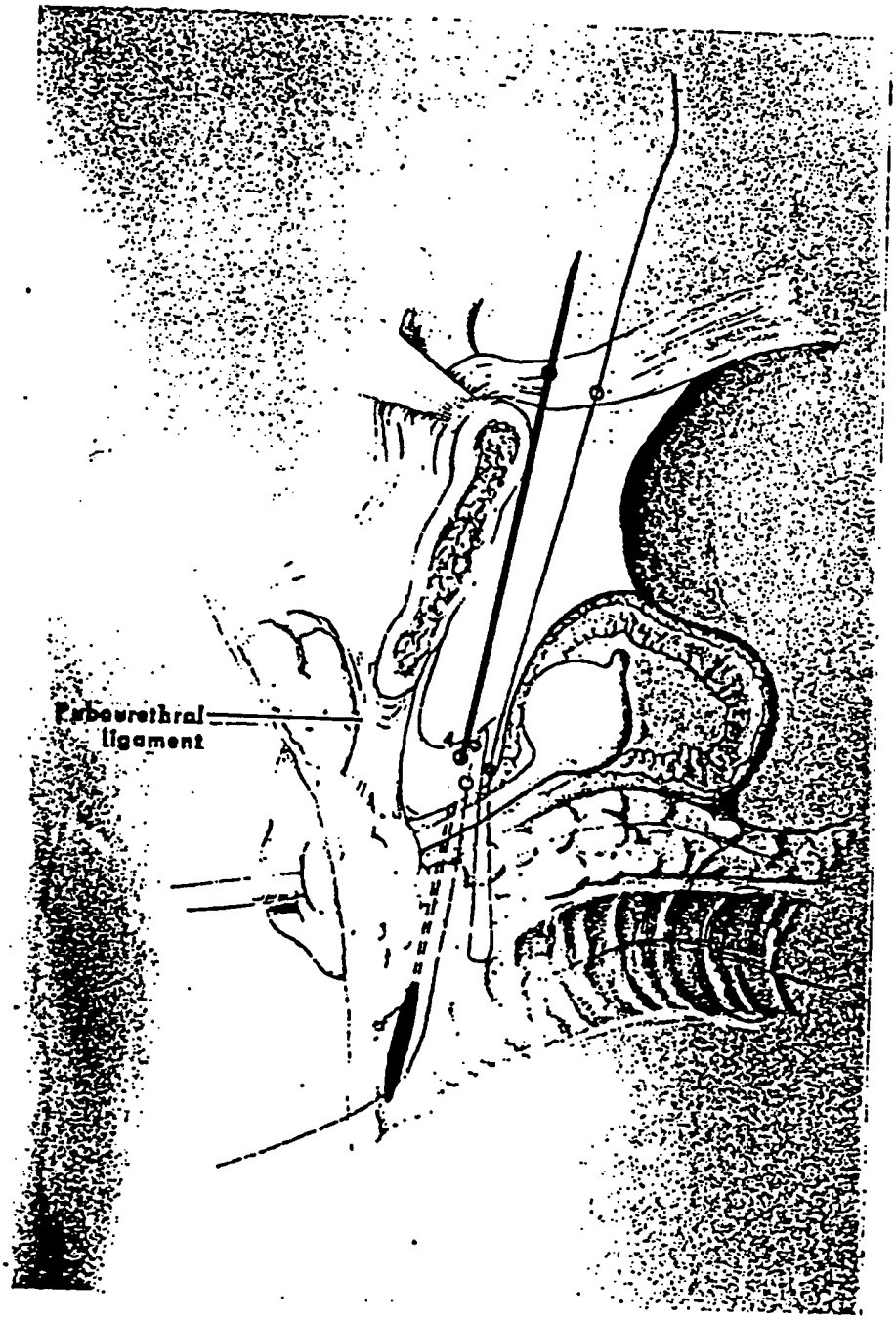
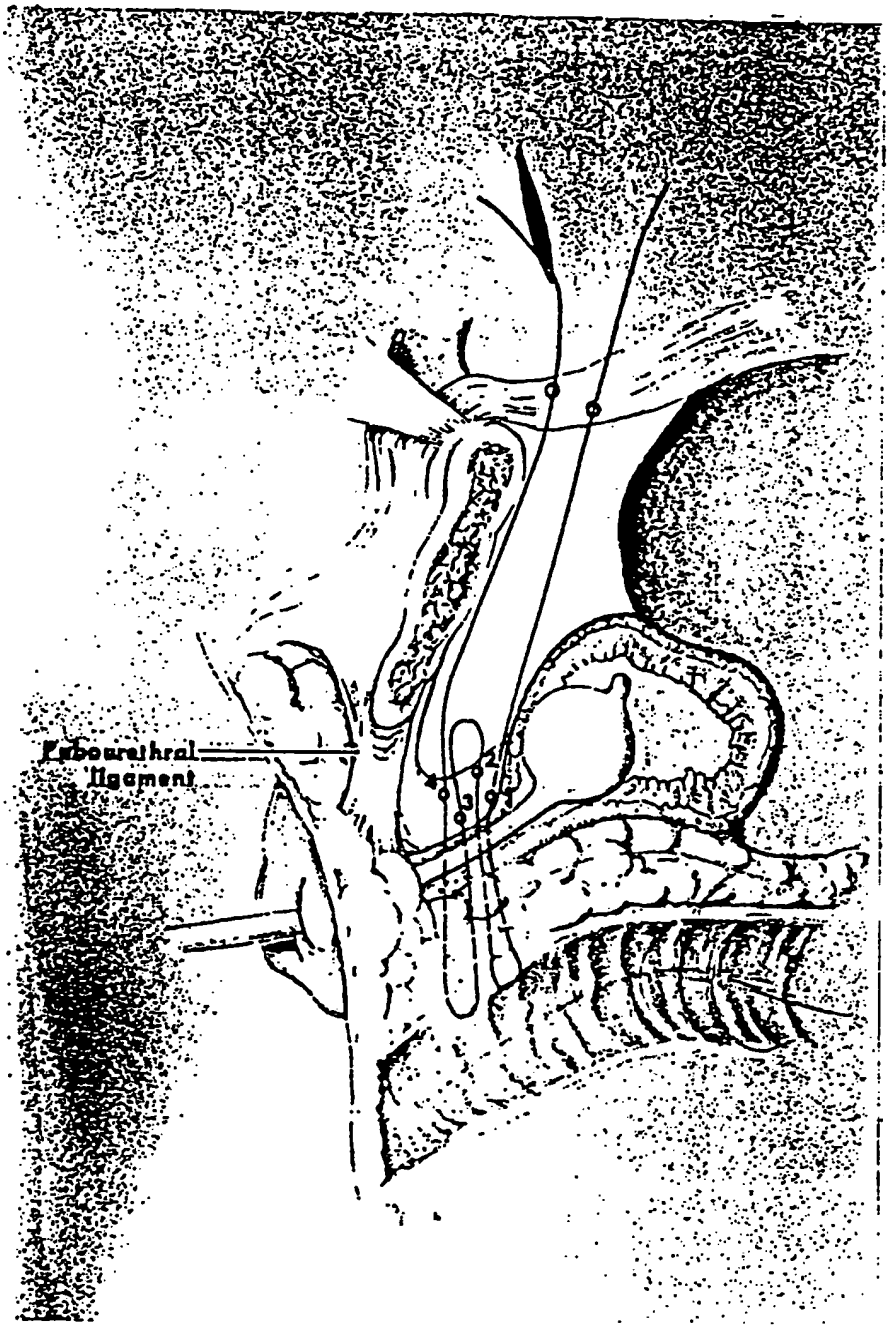


FIG. 5H



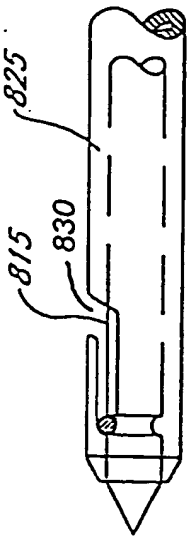


FIG. 6A

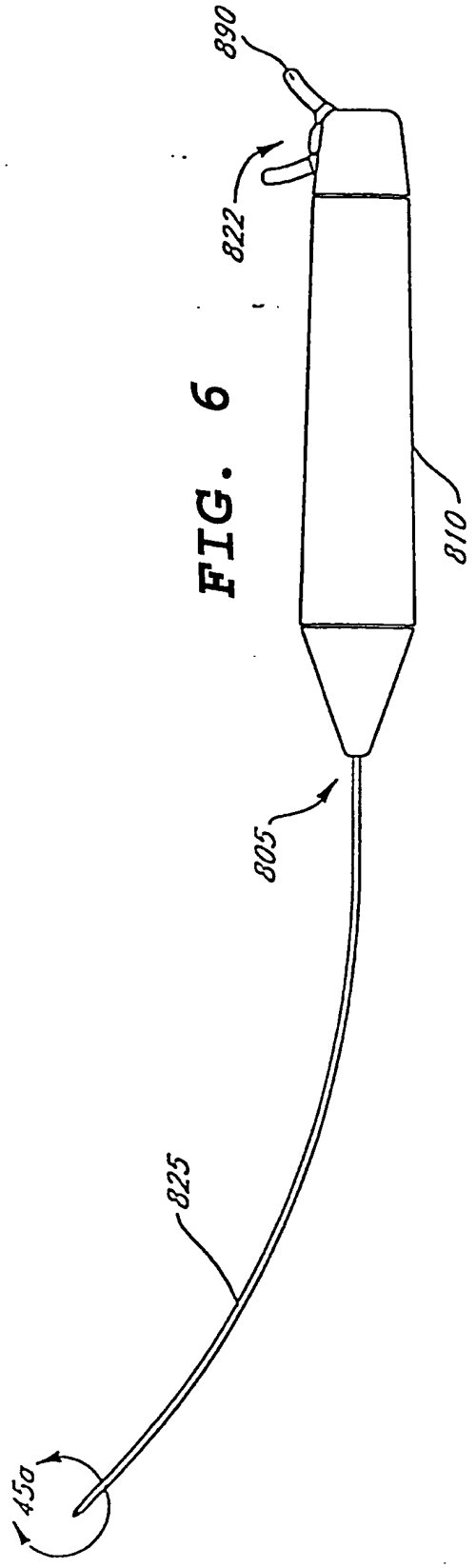


FIG. 6